

Application Serial No.: 09/914,605

## REMARKS

### I. Status Summary

Claims 106-152 are pending in the subject U.S. patent application and have been examined. An Official Action (hereinafter the "Official Action") was issued September 9, 2004 by the United States Patent and Trademark Office (hereinafter the "Patent Office").

In the Official Action, claims 109-112, 138, and 148-151 were objected to as being dependent upon a rejected base claim. According to the Patent Office, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 106 and 108 were rejected under 35 U.S.C. § 101 upon the contention that the claims are directed to non-statutory subject matter.

Claims 106 and 108 were rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by U.S. Patent No. 5,292,524 to Male et al. (hereinafter "the '524 Patent").

Claims 106-108, 113-137, 139-147, and 152 were rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims do not comply with the written description requirement set forth therein.

Claims 1-105 have been canceled without prejudice as being drawn to unelected subject matter. Applicants respectfully reserve the right to file one or more continuation application directed to the subject matter encompassed by claims 1-105.

Claims 106, 109, 118-121, 138, 139, 140, 142, and 148 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly in the claims as filed. Claim 140 was amended to correct a typographical error. Additional support can be found in Section C of the Detailed Description (entitled "Delivery Vehicles for Active Agents") beginning on page 13 (disclosing a variety of isolated, purified, and/or recombinant delivery vehicles), and on page 8, line 28, through page 9, line 4 (representative radiation-inducible targets).

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New claims 153-184 have been added. Support for the amendments can be found throughout the specification as filed, including particularly in the original claims. Additional support can be found on page 8, line 28, through page 9, line 4 (radiation-inducible targets), page 6, lines 16-20 (delivery vehicles can comprise antibodies that bind to radiation-inducible targets), page 21, lines 10-22 (antibodies and derivatives thereof), page 22, lines 1-22 (additional antibody derivatives and monoclonal antibodies), and on page 26, line 13, through page 28, line 7 (single chain antibodies, humanized antibodies, and scFv antibodies that bind radiation-inducible targets).

Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

## II. Responses to the Objections to the Claims

Claims 109-112, 138, and 148-151 have been objected to as being dependent upon a rejected base claim. According to the Patent Office, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully submit that that claims 109 and 138 have been amended to independent form to include the elements of rejected base claim 106. Applicants respectfully submit that the amendments to claims 109 and 138 address the instant objection to claims 109-112 and 138. Similarly, claim 148 has been amended to independent form to include all of the elements of rejected base claims 142 and 147.

Accordingly, applicants respectfully submit that claims 109-112, 138, and 148-151 are now in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

## III. Response to the Rejection under 35 U.S.C. § 101

Claims 106 and 108 have been rejected under 35 U.S.C. § 101 upon the contention that the claims are directed to non-statutory subject matter. The Patent

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Office asserts that the claims read on platelets. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

According to the Patent Office,

Since platelets bind to radiation-damaged tissue, and thus must be binding a target which is induced ("inducible") in that tissue by said radiation, and since the platelet has a normal function in damage repair which would lead to the platelet itself, as well as proteins it normally expresses, being an "active agent", then said platelet would meet the features of the delivery vehicle of claim 106.

Official Action at page 2. Thus, it would appear that the instant rejection is based on the Patent Office's assertion that the claims read on *in vivo*, naturally occurring platelets.

Although applicants do not necessarily agree with this assertion, claim 106 has been amended to recite delivery vehicles comprising a targeting agent and a pharmaceutically acceptable diluent or excipient. Support for the amendment to claim 106 can be found on page 49, lines 27-30 of the specification as filed.

Applicants respectfully submit that the recitation of the delivery vehicle comprising a targeting agent and a pharmaceutically acceptable carrier or excipient addresses the instant rejection of claim 106. Applicants further respectfully submit that that claim 108 depends directly from claim 106, and thus also includes this element.

Accordingly, applicants respectfully submit that the rejection of claims 106 and 108 under 35 U.S.C. § 101 has been addressed, and that the claims are in condition for allowance. A Notice of Allowance to this effect is respectfully solicited.

#### IV. Response to the Rejection under § 102(b)

Claims 106 and 108 have also been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by the '524 Patent. According to the Patent Office, the claims read on platelets as found in nature, and the '524 Patent

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discloses platelets at column 1, lines 16-21. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that independent claim 106 has been amended to recite that the delivery vehicle comprises a targeting agent and a pharmaceutically acceptable carrier or excipient, which applicants respectfully submit that are not disclosed in the '524 Patent. Accordingly, it is believed that claim 106 has been patentably distinguished from the '524 Patent. Furthermore, claim 108 depends directly from claim 106, and thus includes the distinguishing element.

Accordingly, applicants respectfully submit that the rejection of claims 106 and 108 under 35 U.S.C. § 102(b) over the '524 Patent has been addressed, and that the claims are in condition for allowance at this time. A Notice of Allowance to that effect is respectfully requested.

V. Response to the Rejection under 35 U.S.C. § 112

Claims 106-108, 113-137, 139-147, and 152 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims encompass subject matter that is not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventors had possession of the claimed invention. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that the Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement (66 Federal Register 1099; hereinafter "The Guidelines") states that there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed. Furthermore, The Guidelines state that with regard to claims to a genus, "the written description requirement for a

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claimed genus may be satisfied through sufficient description of a representative number of species".

According to the Patent Office:

However, neither the art nor the specification teaches the structures of such molecules beyond fibrinogen, ICAM-1, P-selectin, E-selectin and  $\beta_3$  integrin, as well as the entire delivery vehicle being a platelet itself... This is compounded yet further in that the structures of all such radiation-inducible targets were not (and are not) known in the art, nor disclosed in the specification.

Official Action at page 4. Thus, it appears that the Patent Office concedes that the specification discloses ICAM-1, P-selectin, E-selectin, and  $\beta_3$  integrin as radiation-inducible targets. Applicants further respectfully submit that the specification discloses that cell adhesion molecules and activated platelets themselves are radiation-inducible targets. See Specification at page 8, line 28, through page 9, line 4. Thus, applicants respectfully submit that cell adhesion molecules, ICAM-1, P-selectin, E-selectin, and  $\beta_3$  integrin, and activated platelets are disclosed in the specification as radiation inducible targets, and further that these targets amount to a "representative number" is radiation inducible targets sufficient to satisfy the written description requirement.

As a result, applicants respectfully submit that the instant rejection of claims 106-108, 113-137, 139-147, and 152 under 354 U.S.C. § 112, first paragraph, has been addressed, and that the claims are in condition for allowance at this time.

#### VI. Discussion of the New Claims

New claims 153-184 have been added. Support for the amendments can be found throughout the specification as filed, including particularly in the original claims. Additional support can be found on page 8, line 28, through page 9, line 4 (radiation-inducible targets), page 6, lines 16-20 (delivery vehicles can comprise antibodies that bind to radiation-inducible targets), page 21, lines 10-22 (antibodies and derivatives thereof), page 22, lines 1-22 (additional antibody derivatives and monoclonal

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antibodies), and on page 26, line 13, through page 28, line 7 (single chain antibodies, humanized antibodies, and scFv antibodies that bind radiation-inducible targets).

With regard to new claims 153, 154, 183, and 184, applicants respectfully submit that the new claims are patentably distinguishable over the '524 Patent for reasons similar to those discussed hereinabove with regard to claims 106 and 108. More particularly, applicants respectfully submit that the '524 Patent does not disclose a delivery vehicle comprising a targeting agent and a pharmaceutically acceptable carrier or excipient as recited in claims 106 and 142, the claims from which new claims 153, 154, 183, and 184 depend.

With respect to new claims 155-182, applicants respectfully submit that these claims all depend directly or indirectly from claim 138, which applicants respectfully submit has been amended to independent form to include elements that the Patent Office indicated would put claim 138 in condition for allowance. Applicants respectfully submit that claims 155-182 thus are also believed to be in condition for allowance based on their dependence from claim 138.

Because the cited references do not teach each and every element of the new claims, applicants respectfully submit that new claims 153-184 have been patentably distinguished over the '524 Patent. Accordingly, applicants respectfully submit that claims 153-184 are also in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

#### CONCLUSIONS

In light of the above Amendments and the Remarks presented hereinabove, it is respectfully submitted that claims 106-152 are in proper condition for allowance, and such action is earnestly solicited.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be

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resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

Deposit Account

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

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Date:

Feb. 8, 2005

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